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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/727,461	12/04/2000	Marc Hendriks	P-8573	6569

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EXAMINER	
NGUYEN, DAVE TRONG	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/727,461	HENDRIKS, MARC	
	Examiner	Art Unit	
	Dave T Nguyen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *27 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-26,28-50,53 and 54* is/are pending in the application.

4a) Of the above claim(s) *7,15-24,31,39-48,53 and 54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,6,8-14,25-30,32-38,49 and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claims 3, 27, 51-52 have been canceled, claims 1, 2, 25, and 49 have been amended by the amendment filed October 27, 2003.

Claims 1, 2, 4, 5-26, 28-50, 53, 54 are pending.

Claims 7, 15-24, 31, 39-48, 53, 54 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected claimed invention or species (claims 7 and 31). A complete response to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) MPEP 821.01.

Claims 1, 2, 5, 6, 8-14, 25-30, 32-38, 49, 50 are pending for examination.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 25, 26, 28, 29, 32-33, 49 are rejected under 35 USC 103(a) as being unpatentable over Brown, III *et al.* (US 6,219,577 B1, referred as Brown) taken with Siman *et al.* (US 6,273,875 B1).

Brown teaches a medical device composed of a catheter-based device coupled with a pulse generator for use to enhance the delivery of any pharmaceutical known in the prior art such as plasmids, genes to a target cell, wherein the plasmids or genes are incorporated within a polymer matrix such as any known synthetic polymer, *e.g.,* polyglycoglides, entire disclosure, abstract, column 3, lines 31-67, column 4 through column 5, column 13, last full paragraph, and entire column 15. On the basis of the Brown's teaching, for example, column 5, line 50, which teaches an insertion (same as implantation) of the catheter into a patient), and of the prior art exemplified by Siman, column 4, lines 40-42, the catheter of Brown is an implantable catheter.

Brown does not teach the newly added limitation which recites that the catheter must have a polymer film applied to the exterior surface of the implantable medical device housing.

However, at the time the invention was made, Siman teach by applying a polymer film on the surface of part or all a medical device including its body, the medical device would have improved antimicrobial/antithrobogenic properties, see first

paragraph, column 1, column 3, lines 54-63. As such, the body of the catheter, which is coated with an antimicrobial and antithrombogenic polymer, is the same as the housing of the claimed medical device, which clearly embrace a catheter as a medical device.

It would then have been obvious for one of ordinary skill in the art to incorporate a suitable antimicrobial and antithrombogenic polymer film, as taught in the prior art exemplified by Siman, on the surface of the cathether of Brown, which may be exposed to an *in vivo* environment during its insertion into a patient for delivering of a polynucleotide to the patient. One of ordinary skill in the art would have been motivated to do so because Siman teach by applying a polymer film on the surface of part or all a medical device including its body, the medical device would have improved antimicrobial/antithrobogenic properties. These properties would thereby reduce infection caused by medical devices such as the catheter of Brown.

Thus, the claimed invention was *prima facie* obvious.

Claims 1, 2, 4, 5, 8, 9, 10, 25-28, 29, 32, 33, 35, 49-50 are rejected under 35 USC 103(a), as being unpatentable over Brown, III *et al.* (US 6,219,577 B1, referred as Brown) taken with Siman and Gunzburg (WO 96/28563).

To the extent that the claims are readable to the claimed medical device, wherein the polynucleotide encodes an antimicrobial peptide, Brown taken with Siman are applied here as indicated above. Brown taken with Siman does not teach that the polynucleotide encodes an anti-microbial peptide. However at the time the invention was made, Gunzburg teaches genes encoding antimicrobial peptides can be used in

gene therapy for the treatment of mammalian tumours, viral infections, entire disclosure, especially pages 6-7.

It would have been obvious for one of ordinary skill in the art to incorporate a polynucleotide encoding an anti-microbial peptide into the polymer coating contained within the catheter of Brown taken with Siman.

One of ordinary skill in the art would have been motivated to do so because not only the anti-microbial peptide DNA associated with a polymer coated catheter of Brown taken with Siman can be used to treat a viral invention, as taught by Gunzburg, the anti-microbial peptide encoded DNA when present within the polymer coated housing would reduce an infection by any virally infectious agent present on the medical device of Brown taken with Siman.

Thus, the claimed invention as a whole was *prima facie* obvious.

Claims 1, 4-6, 25, 28-30 are rejected under 35 USC 103(a) as being unpatentable over Brown taken with Siman and Gunzburg, and further in view of either Naghavi (US Pat No. 6,451,044 B1) or Soykan (US Pat No. 6,206,914 B1).

To the extent that the claims are readable to the claimed medical device, wherein the polynucleotide is entrapped within a natural porous polymer such as collagen, Brown taken with Siman and Gunzburg is applied has indicated above. Brown taken with Siman and Gunzburg does not teach that the polymer applicable for use to enhance the delivery of genes and/or plasmids is a natural porous polymer such as

collagen, both Naghavi and Soykan teach that medical devices comprising a natural porous polymer such as collagen is well suitable for use in enhancing the delivery of therapeutic DNA to a target cell (entire disclosure, particularly column 22 and column 10, last full par., respectively).

It would have been obvious for one of ordinary skill in the art to employ the catheter based medical device comprising a natural porous polymer such as collagen to enhance the delivery of any therapeutic DNA to a target cell. One of ordinary skill in the art would have been motivated to employ the catheter based medical device composed of a natural porous polymer such as collagen in the delivery of any therapeutic DNA to a target cell because Brown, for example, teaches that a medical device composed of a catheter-based device comprising any polymeric matrix known in the prior art can be used to enhance the delivery of any pharmaceutical known in the prior art such as plasmids, genes to a target cell, and because Naghavi and Soykan teach that medical devices comprising a natural porous polymer such as collagen is well suitable for use in enhancing the delivery of therapeutic DNA to a target cell (entire disclosure).

Thus, the claimed invention as a whole was *prima facie* obvious.

Claims 1, 2, 4, 5, 8, 9, 10-14, 25-26, 28, 32-38, 49-50 are rejected under 35 USC 103(a) as being unpatentable over Brown taken with Siman and German (US 2003/0078266 A1).

To the extent that the claims are readable to the claimed medical device, wherein the polynucleotide encodes an antimicrobial peptide, Brown taken with Siman is applied

has indicated above. Brown does not teach that the polynucleotide encodes a microbial peptide, however, German teaches genes encoding antimicrobial peptides can be used in gene therapy for the treatment of microbioal infection, page 6, par.0083 and 0085.

It would have been obvious for one of ordinary skill in the art to incorporate a polynucleotide encoding an anti-microbial peptide into the polymer coating contained within the catheter of Brown taken with Siman.

One of ordinary skill in the art would have been motivated to do so because not only the anti-microbial peptide DNA associated with a polymer coated catheter of Brown taken with Siman can be used to treat a viral invention, as taught by German, the anti-microbial peptide encoded DNA when present within the polymer coated housing would reduce an infection by any virally infectious agent present on the medical device of Brown taken with Siman.

To the extent that the claims are readable to the claimed medical device, wherein the polynucleotide is condensed, linked to a targeting ligand, or complexed to a liposomal carrier, Brown is applied has indicated above. Brown does not teach that the polynucleotide is condensed, linked to a targeting ligand, or complexed to a liposomal carrier. However at the time the invention was made, German teaches that lipsomal carrier comprising a therapeutic DNA, and that therapeutic DNA conjugated to polylysine and a targeting ligand are routinely used in the prior art to preserve and enhance the delivery of the DNA to a target cell (page 7, pars. 0095 and 0096).

It would have been obvious for one of ordinary skill in the art to employ the catheter based medical device of Brwon to deliver a liposomal carrier or a condensed

DNA/polylysine/targeting complex to enhance the delivery and expression any therapeutic DNA including those encoding an antimicrobial polypeptide to a target cell. One of ordinary skill in the art would have been motivated to employ the catheter based medical device of Brown in the delivery of any therapeutic DNA complex such as those described in German to a target cell because Brown teaches that a medical device composed of a catheter-based device comprising any carrier known in the prior art can be used to enhance the delivery of any pharmaceutical known in the prior art such as plasmids, genes to a target cell, and because German not only teaches that liposomal carriers complexed to any desired therapeutic DNA including those encoding a microbial peptide can be used to enhance and preserve the delivery and expression of the DNA, but also teaches that a condensed DNA/polylysine/targeting complex is well suitable for use in enhancing the delivery of any therapeutic DNA to a target cell.

Thus, the claimed invention as a whole was *prima facie* obvious.

Applicant 's response has been considered by the examiner but is moot in view of the new grounds of the rejection.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

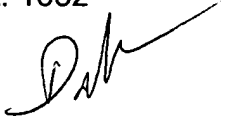
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051.**

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Please note that the examiner is expected to move to a new US PTO office building located in Alexandria on January 12, 2004. The examiner office phone number at the new building is **571-272-0731.**

Dave Nguyen
Primary Examiner
Art Unit: 1632



DAVE T. NGUYEN
PRIMARY EXAMINER